

### Remarks

Claims 5 and 40 have been amended, new claims 45 and 46 have been added, and therefore claims 1, 3-6, 31, and 33-47 are pending in this application. The Examiner's allowance of claims 31, 33-39 and 41-44 is gratefully acknowledged. It is respectfully submitted that the remaining claims (1, 3-6, 40 and 45-47) are also allowable.

Claims 5 and 40 have been amended only where believed necessary to render the language of each claim more consistent with the independent claim, and new claims 45-47 each have been added to further point out the corresponding structure for the respective means-plus-function recitation disclosed in the specification. Accordingly, no new matter has been added, and these amendments are believed to be proper and should be entered under 37 C.F.R. § 1.116.

The undersigned thanks Examiner Alexander for courteously discussing this patent application on March 7, 2001, during which the apparatus claims were discussed with reference to the prior art. As was discussed, the limitations of independent claim 1 are drafted in "means-plus-function" format, and therefore under 35 U.S.C. § 112 and In re Donaldson Co., 16 F.3d 1994 (Fed. Cir. 1994), each such limitation "shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112, paragraph 6. Further, in order to reject this claim, the Examiner must show with respect to each means-plus-function limitation, that the cited prior art teaches employing the same or equivalent structure to that disclosed in the specification for performing the recited function, and that the cited prior art further teaches or suggests using such structure to perform said function. In re Donaldson Co., 16 F.3d 1994 (Fed. Cir. 1994); and M.P.E.P. § 2182.

Accordingly, it is respectfully submitted that the Examiner's assertion that the functional language recited in claim 1 is "of no patentable moment" is incorrect. To the contrary, the

functional language defines the invention under § 112, and must be considered in determining patentability in the manner outlined above.

As was also discussed, Tsuji et al. (U.S. No. 4,420,564) neither teach nor suggest means for pumping each of a plurality of reagent-mixture components in a respective stream at a respective predetermined flow rate, as recited in independent claim 1. To the contrary, Tsuji et al. show in FIG. 3 a single pump 3 for flushing the buffer liquid through the cell CE. There is simply no teaching or suggestion in Tsuji et al. of pumping each reagent-mixture component in a respective stream at a respective predetermined flow rate. Rather, Tsuji et al. teach mixing the components together in the cell CE, analyzing the components in the cell, and after the analyses is completed, and only then, do Tsuji et al. teach using the pump 3 to flush all of the mixed components from the cell.

Tsuji et al. likewise fail to teach or suggest means for combining at least one reagent-mixture component stream into a stream of at least one other reagent-mixture component stream for mixing the plurality of reagent-mixture components into a combined reagent-mixture stream, as further recited in independent claim 1. To the contrary, Tsuji et al. simply teach putting the components into the cell CE in accordance with a "standard concentration". Moreover, the blood sample is introduced into the reaction cell CE through the inlet OP in FIG. 3, which is simply a round aperture for receiving an instrument (not shown) therethrough for introducing the blood sample. There is no teaching or suggestion whatsoever in Tsuji et al. of any of the various structures disclosed in the present specification, or equivalents thereof, for performing the combining function recited in this limitation of the claim.

In addition, Tsuji et al. also fail to teach or suggest means for forming each of a plurality of different selected reagent mixtures in the combined reagent-mixture stream by adjusting the

flow rate of at least one of a plurality of reagent-mixture components in accordance with a flow-rate ratio of reagent-mixture components corresponding to each respective selected reagent mixture, as further recited in amended independent claim 1. To the contrary, Tsuji et al. expressly contemplate putting the ingredients in the reaction cell CD in accordance with a "standard concentration", and make no teaching or suggestion of adjusting the flow rates of the reagent-mixture components in accordance with selected flow-rate ratios.

It is therefore respectfully submitted that independent claim 1 is neither anticipated nor rendered obvious over Tsuji et al. for at least these reasons. Because each of claims 3-6, 40 and 45-47 includes all of the limitations of independent claim 1, it is respectfully submitted that these dependent claims likewise are not anticipated by Tsuji et al. for at least the same reasons as the independent claim, and for reciting additional patentable subject matter.

Neither Surjaatmadja et al. (U.S. No. 5,192,509) nor Sainz et al. (4,804,519) likewise teach or suggest the present invention as recited in independent claim 1. Surjaatmadja et al. is concerned with identifying particular elements through titration of well bore fluid through a color detector. Accordingly, Surjaatmadja et al. do not discuss in any way analyzing blood or blood samples, much less discuss chemically analyzing or analyzing particle distributions of a reagent mixture component including a sample of blood, as recited in independent claim 1.

Similarly, Sainz et al. is concerned with material spectrometry via a torch 52 and use of the diluent kerosene, and does not discuss in any way analyzing blood or blood samples, as recited in independent claim 1.

Accordingly, it is respectfully submitted that independent claim 1 is neither anticipated nor rendered obvious over Surjaatmadja et al. or Sainz et al. for at least these reasons. Because each of claims 3-6, 40 and 45-47 includes all of the limitations of independent claim 1, it is

respectfully submitted that these dependent claims likewise are neither anticipated by nor rendered obvious over Surjaatmadja et al. or Sainz et al. for at least the same reasons as the independent claim, and for reciting additional patentable subject matter.

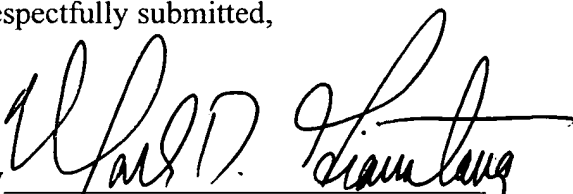
It is therefore respectfully submitted that claims 1, 3-6, 40 and 45-47 are allowable in addition to the claims already allowed. All issues raised by the Examiner having been addressed, an early action to that effect is earnestly solicited.

If the Examiner has any questions concerning any of the issues herein, or otherwise if it would facilitate the examination of this application, the Examiner is respectfully urged to call the undersigned at the telephone number below.

No fee in addition to that submitted herewith is believed to be required; however, if an additional fee is required, or otherwise if necessary to cover any deficiency in fees paid, authorization is hereby given to charge our deposit account no. 50-1631.

Respectfully submitted,

By



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**Version With Markings To Show Changes Made**

**In the Specification:**

On page 7, please substitute the following paragraph for the paragraph at lines 15-25:

The valve matrix 16 is also connected through a plurality of injection/aspiration lines 22 to a flow-injection unit 24 for introducing or combining at least one reagent-mixture component into a stream of at least one other reagent-mixture component in order to immediately thoroughly and uniformly mix the components and create a reagent mixture, as is described in detail below. The flow-injection unit 24 is coupled through a reagent-mixture injection line 26 to a sensing unit 28 for detecting differences in electrical, optical, chemical or other characteristics of particles in the reagent mixture, and generating signals having characteristics relating to the differences.

On page 8, please substitute the following paragraph for the paragraph at lines 7-17:

As also shown in FIG. 1, a processing and control unit 34 is coupled to each of the pump units 12, the valve matrix 16 and sensing unit 28 to control operation of each component, analyze the data, and provide analysis results. The sensing unit 28 is preferably of the type disclosed in U.S. Patent No. 5,380,491, entitled "Apparatus For Pumping And Directing Fluids For Hematology Testing", and U.S. application serial no. 08/370,023, filed January 9, 1995, now U.S. Patent No. 5,728,351, which is a divisional of U.S. Patent No. 5,380,491, both of which are assigned to the Assignee of the present invention, and are hereby expressly incorporated by reference as part of the present disclosure.

On page 9, please substitute the following paragraph for the paragraph at lines 7-18:

In hematologic analysis, the sensing unit 28 includes a transducer for counting the white blood cells and measuring their volume (size) and/or opacity by electrical or optical differences.

The blood cells are counted for a period of time to gather sufficient data for analysis, and the data is stored and analyzed in the processing and control unit 34 to determine the parameters of the constituent subpopulations of the reagent-mixture sample. The processing and control unit 34 is preferably constructed and operates in accordance with the apparatus and method disclosed in U.S. Patent Nos. 5,187,673 and 5,349,538, both of which [are assigned to Edward L. Carver, Jr., and] are hereby expressly incorporated by reference as part of the present disclosure.

On page 11, please substitute the following paragraph for the paragraph at lines 12-20:

In order to minimize fluid waste and in turn further minimize the volume of reagent-mixture components necessary for analysis, the valves employed in the valve matrix 16 preferably exhibit zero dead volume. A preferred type of zero dead volume valve is disclosed in co-pending patent application serial no. 08/385,145, filed February 7, 1995, now U.S. Patent No. 5,542,452, entitled "Valve Assembly", which is assigned to the Assignee of the present invention, and is hereby expressly incorporated by reference as part of the present disclosure.

On page 14, please substitute the following paragraph for the paragraph at lines 3-12:

Exemplary reagent-mixture components and the preferred methods for employing these components are disclosed in U.S. Patent No. 5,262,329, entitled "METHOD FOR IMPROVED MULTIPLE SPECIES BLOOD ANALYSIS", dated November 16, 1993, U.S. Patent No. 5,316,725, entitled "REAGENT SYSTEM FOR THE IMPROVED DETERMINATION OF WHITE BLOOD CELL SUBPOPULATIONS", dated May 31, 1994, and U.S. Patent No. 5,316,951, entitled "METHOD FOR THE IMPROVED DETERMINATION OF WHITE BLOOD CELL SUBPOPULATIONS", dated May 31, 1994, which are each [assigned to Edward L. Carver, Jr., and are] hereby expressly incorporated by reference as part of the present disclosure.

**In the Claims:**

Please amend claims 5 and 40 by substituting each of the following claims for the corresponding pending claims:

5. (Amended) An apparatus as defined in claim 1, [further comprising] wherein the means for forming comprises a control unit coupled to the means for pumping and including a database of predetermined reagent-mixture ratios, wherein each predetermined reagent-mixture ratio corresponds to one or more animal species, and the control unit is responsive to an input for a selected animal species to control the means for pumping to pump the reagent-mixture components of the respective reagent-mixture ratio of the selected animal species at a flow-rate ratio corresponding to the reagent-mixture ratio.

40. (Amended) An apparatus as defined in claim [2] 1, wherein the means for forming forms the selected reagent mixture [is formed] by adjusting the flow rates of at least two reagent-mixture components in accordance with the respective flow-rate ratio.

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